Complete Summary

GUIDELINE TITLE

Contraception for women aged over 40 years.

BIBLIOGRAPHIC SOURCE(S)

Contraception for women aged over 40 years. J Fam Plann Reprod Health Care 2005 Jan; 31(1):51-63; quiz 63. [147 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

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SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Counseling Management Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Nurses Patients Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations to guide clinicians, women, and couples in making decisions about contraceptive choices for women aged over 40 years

TARGET POPULATION

Women aged over 40 years considering the use of contraception

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Assessment of patient's medical eligibility for contraceptive use
- 2. Counseling and educating women about the risks and benefits of contraceptive use
- 3. Combined hormonal contraception
- 4. Progesteron-only contraception
- 5. Sterilization
- 6. Barrier contraception
- 7. Copper intrauterine contraception
- 8. Yearly follow-up visits for women using contraception
- 9. Stopping non-hormonal and hormonal contraception

Note: Guideline developers discussed but did not recommend natural family planning methods of contraception.

MAJOR OUTCOMES CONSIDERED

- Risks associated with hormonal contraceptive use in women aged over 40 years
- Risks of sterilization and intrauterine device (IUD) contraception
- Non-contraceptive benefits of hormonal contraception
- Efficacy of various contraceptive methods
- Average age of menopause

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed in general between 1990 and 2004 for MEDLINE (CD Ovid version); EMBASE (1990-2004); PubMed; the Cochrane Library (to September 2004), and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms, and text words. The Cochrane Library was searched for systematic reviews, meta-analyses, and controlled trials relevant to contraception for women aged over 40 years. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO), and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organizations.

Evidence tables (available on the Faculty Web site [www.ffprhc.org.uk]) summarise relevant published evidence on contraception for women aged over 40 years, which was identified and appraised in the development of this Guidance.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of recommendation are based on levels of evidence as follows:

- A: Evidence based on randomised controlled trials (RCTs)
- B: Evidence based on other robust experimental or observational studies
- C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of recommendation, based on levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

Do sexually active women aged over 40 years still require contraception?

- 1. Women should be informed that although a natural decline in fertility occurs from the age of 37 years, effective contraception is required to prevent unplanned pregnancy (Grade B).
- 2. Women should be informed that the risks of congenital and chromosomal abnormalities, spontaneous abortion, pregnancy complications, and of maternal morbidity and mortality increase for women over the age of 40 years (Grade B).

How can a clinician assess medical eligibility for contraceptive use by a woman aged over 40 years?

3. A clinician should take a clinical history (including sexual history) to allow assessment of contraceptive options, taking account of cardiovascular and cerebrovascular disease and neoplasia, which increase with increasing age (Good Practice Point).

Which contraceptive methods can be used by a woman aged over 40 years?

- 4. Women aged over 40 years can be advised that no contraceptive method is contraindicated by age alone (Grade C).
- 5. Women aged over 40 years should be advised of the risks and non-contraceptive benefits of all contraceptive methods (Grade C).

Combined Hormonal Contraception

6. Women aged over 40 years can be advised that combined hormonal contraception can be used unless there are co-existing diseases or risk factors (Grade B).

Risks Associated with Combined Hormonal Contraceptive Use

Cardiovascular and Cerebrovascular Disease

- 7. Non-smokers at any age with no specific risk factors can be advised that they have no increased risk of myocardial infarction (MI) with combined oral contraception (COC) use (Grade B).
- 8. The risks of using combined hormonal contraception outweigh the benefits for smokers aged 35 years or older (Grade C).
- 9. Women aged 35 years or older with no other risk factors who have stopped smoking more than a year ago may consider using combined hormonal contraception. The excess risk of myocardial infarction (MI) associated with smoking falls significantly 1 year after stopping and is gone 3 to 4 years later, regardless of the amount smoked (Grade B).
- 10. Women should be advised that, although the relative risk of venous thromboembolism with COC use can increase up to five-fold, in absolute terms the risk is still very small (Grade B).
- 11. Women should be advised there is a very small increase in the absolute risk of ischaemic stroke but no increase in haemorrhagic stroke with COC use (Grade B).
- 12. Women aged over 40 years with cardiovascular disease, stroke, or migraine (even without aura) should be advised against the use of combined hormonal contraception (Grade C).
- 13. Clinicians prescribing COC to women aged over 40 years should consider a monophasic pill with ≤30 microgram ethinylestradiol with a low dose of norethisterone or levonorgestrel as a suitable first-line option (Good Practice Point).

Breast cancer

14. Women aged over 40 years should be advised that any increase in risk of breast cancer associated with COC use is likely to be small, is reduced to no

excess risk 10 years after stopping, but is in addition to their own background risk, which increases with age (Grade B).

Cervical Cancer

15. Women should be advised that COC use appears to increase the risk of cervical cancer and cervical intraepithelial neoplasia after 5 years' use (Grade B).

Non-Contraceptive Benefits Associated with Combined Hormonal Contraceptive Use

Bone Health

16. Women can be advised that COC use over the age of 40 years may be associated with an increase in bone mineral density (Grade B).

Ovarian and Endometrial Cancers

17. Women can be advised of at least a 50% reduction in risk of ovarian and endometrial cancer with COC use, which continues for 15 years after stopping (Grade B).

Colorectal Cancer

18. Women can be advised that there is a reduction in the risk of colorectal cancer with COC use (Grade B).

Benign Breast Disease

19. Women can be advised that there may be a reduction in the incidence of benign breast disease with COC use (Grade B).

Menstrual Bleeding Patterns

20. Women can be advised that, in clinical practice, menstrual bleeding and pain may be reduced with COC use (Grade B).

Vasomotor symptoms

21. Women can be advised that, in clinical practice, COC may reduce hot flushes (Grade C).

Progestogen-Only Contraception (POC)

Potential Risks Associated with POC

Cardiovascular and Cerebrovascular Disease

- 22. Women should be advised that, although data are limited, there is no apparent increase in risk of cardiovascular disease (MI, venous thromboembolism [VTE]) or stroke with POC (Grade B).
- 23. Women with current VTE should be advised that the risks of using progestogen-only methods outweigh the benefits. Women with previous VTE, however, can be advised that the benefits of using progestogen-only methods outweigh the risks (Grade C).
- 24. Women with a history of ischaemic heart disease or stroke should be advised that the risks of initiating a progestogen-only injectable outweigh the benefits; however, the benefits of initiating progestogen-only pills (POPs), implants, or the levonorgestrel-releasing intrauterine system (LNG-IUS) outweigh the risks (Grade C).

Breast Cancer

25. Women can be advised that the limited evidence currently available does not suggest a significant increase in the risk of breast cancer with POPs and injectables. The use of implants and the LNG-IUS are unlikely to pose an increased risk (Grade C).

Bone Health

- 26. Women can be advised that long-term use of progestogen-only injectable contraception is associated with a reduction in bone mineral density (BMD) but this returns to normal after cessation (Grade B).
- 27. The relationship between bone densitometry and fracture risk in women aged over 40 years who are using injectable POC is unclear (Grade C).

Bleeding Patterns

28. Women should be advised that irregular bleeding is a common side effect with POC. Clinicians should carefully consider when the investigation of abnormal bleeding may be indicated in women aged over 40 years (Grade C).

Sterilisation

- 29. Counseling and advice on sterilisation procedures should be provided to women and men within the context of a service providing a full range of information and access to other long-term reversible methods of contraception. This should include information on the advantages and disadvantages and relative failures (Grade C) (Royal College of Obstetricians and Gynecologists [RCOG], 2004).
- 30. Women should be informed that vasectomy carries a lower failure rate and that there is less risk related to the procedure (Grade B) (RCOG, 2004).

Tubal Occlusion

31. Women, particularly those at increased risk from conditions such as previous abdominal surgery or obesity, should be informed of the risks of laparoscopy and the chances of laparotomy being necessary if there are problems with the laparoscopy procedure (Grade B) (RCOG, 2004)

- 32. Women should be informed that tubal occlusion is associated with a failure rate and that pregnancy can occur several years after the procedure. The lifetime risk of failure, in general, is estimated to be 1 in 200. The longest period of follow-up data available for the most common method used in the UK, the Filshie clip, suggests a failure rate after 10 years of 2 or 3 per 1,000 procedures (Grade B) (RCOG, 2004).
- 33. Women should be informed that if tubal occlusion fails, the resulting pregnancy may be ectopic (Grade B) (RCOG, 2004)
- 34. Although women requesting sterilisation should understand that the procedure is intended to be permanent, they should be given information about the success rates associated with reversal, should this procedure be necessary (Grade B) (RCOG, 2004).
- 35. Women should be reassured that tubal occlusion is not associated with an increased risk of heavier or longer periods when performed after 30 years of age. There is an association with subsequent increased hysterectomy rate, although there is no evidence that tubal occlusion leads to problems that require hysterectomy (Grade B) (RCOG, 2004)
- 36. Hysteroscopic methods of tubal occlusion are still under evaluation and should only be used within the present guidance system for new surgical interventions (Grade C) (RCOG, 2004).

Vasectomy

- 37. Men should be informed that vasectomy has an associated failure rate and that pregnancies can occur several years after vasectomy. The rate should be quoted as approximately 1 in 2,000 after clearance has been given (Grade B) (RCOG, 2004).
- 38. Although men requesting vasectomy should understand that the procedure is intended to be permanent, they should be given information on the success rates associated with reversal should this procedure be necessary (Grade B) (RCOG, 2004).
- 39. Men should be advised to use effective contraception until azoospermia has been confirmed. The way in which azoospermia is confirmed will depend on local protocols (Grade C) (RCOG, 2004).
- 40. Men requesting vasectomy can be reassured that there is no increase in testicular cancer or heart disease associated with vasectomy. The association in some reports of an increased risk of being diagnosed with prostate cancer is at present considered to be non-causative (Grade B) (RCOG, 2004).
- 41. Men should be informed about the possibility of chronic testicular pain after vasectomy (Grade B) (RCOG, 2004).

Barrier Contraception

42. Women should be advised to use condoms with nonspermicidal lubricant where possible (Grade C).

Copper Intrauterine Contraception

43. Asymptomatic women aged 40 years or older who are having an intrauterine device (IUD) inserted and have been identified as being at higher risk for sexually transmitted infection (STI) should have an endocervical swab for Chlamydia trachomatis as a minimum, together with an endocervical swab for

- Neisseria gonorrhoea, depending on local prevalence. There is no indication to test for other lower genital tract organisms (Grade C).
- 44. Women should be informed that menstrual abnormalities (including spotting, light bleeding, heavy or longer menstrual periods) are common in the first 3 to 6 months of IUD use. Women should be advised to seek medical advice to exclude infection and gynaecological pathology, if menstrual abnormalities occur after the first 6 months of use (Grade C).

When can a woman over the age of 40 years be advised to stop contraception?

- 45. In general, women can be advised to stop contraception at the age of 55 years as most (95.9%) will be menopausal by this age (Grade C).
- 46. Measuring follicle-stimulating hormone on at least two occasions 1 or 2 months apart may predict ovarian failure and be helpful in some situations when advising women when to stop contraception (Grade C).

Stopping Non-hormonal Contraception

- 47. Women using non-hormonal contraception can be advised to stop contraception after 1 year of amenorrhoea (or 2 years if the last menstrual period occurred for a woman aged less than 50 years) (Grade C).
- 48. After counselling about declining fertility, risks associated with IUD insertion, and contraceptive efficacy, women who have an IUD with more than 300 mm² of copper inserted at age 40 years or older can be advised to retain the device until the menopause (Grade C).

Stopping Hormonal Contraception

49. Women using exogenous hormones should be advised that amenorrhoea is not a reliable indicator of ovarian failure (Good Practice Point).

Stopping Combined Contraception

- 50. Women using combined contraception should be advised to switch to another suitable contraceptive method at the age of 50 years (Good Practice Point).
- 51. Follicle-stimulating hormone (FSH) is not a reliable indicator of ovarian failure in women using combined hormones, even if measured during the hormone-free or oestrogen-free interval (Good Practice Point).

Stopping POPs and Implants

52. Women can be advised that a POP or implant can be continued until the age of 55 years when natural loss of fertility can be assumed. Alternatively, the woman can continue with the POP or implant and have FSH levels checked on two occasions 1 or 2 months apart, and if both levels are greater than 30 IU/L this is suggestive of ovarian failure. In this case the woman may continue with the POP, implant or barrier contraception for another year (or 2 years if aged less than 50 years) (Good Practice Point).

Stopping Progestogen-Only Injectables

53. Women should be counselled about the risks and benefits of continuing with the progestogen-only injectable at the age of 50 years and be advised to switch to a suitable alternative) (Good Practice Point).

Removing the LNG-IUS

54. Women who have the LNG-IUS inserted at age 45 years or older for contraception or for the management of menorrhagia can be counseled about retaining the device for up to 7 years (Good Practice Point).

For women using hormone replacement therapy (HRT) is contraception also required?

- 55. Women using combined HRT cannot be advised to rely on this as contraception (Grade B).
- 56. Women can be advised that a POP can be used with HRT to provide effective contraception (Good Practice Point).
- 57. Women using oestrogen replacement therapy may choose the LNG-IUS to provide endometrial protection (Grade A).

What follow-up is required for women over 40 years using contraception?

58. Women aged over 40 years should be advised to return for follow-up if they develop any problems with contraception or develop any new medical history that may influence contraceptive choice or when they reach the age of 50 years (Grade C).

Definitions

Grades of recommendation are based on levels of evidence as follows:

- A: Evidence based on randomised controlled trials (RCTs)
- B: Evidence based on other robust experimental or observational studies
- C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for Advice for Women at Age 50 on Stopping Contraception.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

- Appropriate decision-making about contraceptive choices for women aged over 40 years
- Prevention of unintended pregnancy

Specific Benefits

Non-Contraceptive Benefits Associated with Combined Hormonal Contraceptive Use:

- Combined oral contraceptive pill (COC) use may be associated with an increase in bone mineral density.
- At least a 50% reduction in risk of ovarian and endometrial cancer
- A reduction in the risk of colorectal cancer, benign breast disease, menstrual bleeding and pain, and hot flashes

Non-Contraceptive Benefits of Progesteron-Only Contraception (POC):

• POC may reduce the risk of endometrial and ovarian cancer.

POTENTIAL HARMS

Combined Hormonal Contraception

- Smoking women aged 35 years or older may be at increased risk for cardiovascular and cerebrovascular disease.
- Risk of venous thromboembolism can increase up to five-fold; however, in absolute terms the risk is still very small.
- There is a very small increase in the absolute risk of ischemic stroke.
- Women aged over 40 years with cardiovascular disease, stroke, or migraine (even without aura) should be advised against the use of combined hormonal contraception.
- There is a small increase in risk of breast cancer and increased risk of cervical cancer and cervical intraepithelial neoplasia after 5 years' use.

Progesteron-Only Contraception (POC)

- The risks of using POC in women with current venous thromboembolism outweigh the benefits.
- The risks of initiating a progestogen-only injectable outweigh the benefits in women with a history of ischemic heart disease or stroke.
- Long-term use of progestogen-only injectable contraception is associated with a reduction in bone mineral density (BMD) but this returns to normal after cessation.
- Irregular bleeding is a common side effect of POC.

Sterilization

- Vasectomy carries a lower failure rate than female sterilization and there is less risk related to the procedure.
- Tubal occlusion is associated with a failure rate and pregnancy can occur several years after the procedure. The lifetime risk of failure, in general, is estimated to be 1 in 200.
- If tubal occlusion fails, the resulting pregnancy may be ectopic.
- Tubal occlusion is associated with subsequent increased hysterectomy rate, although there is no evidence that tubal occlusion leads to problems that require hysterectomy
- Vasectomy has an associated failure rate and pregnancies can occur several years after vasectomy. The rate is approximately 1 in 2,000 after clearance has been given.
- There is a possibility of chronic testicular pain after vasectomy.

Copper Intrauterine Contraception

 Menstrual abnormalities (including spotting, light bleeding, heavy or longer menstrual periods) are common in the first 3 to 6 months of intrauterine device (IUD) use.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Staff Training/Competency Material

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Contraception for women aged over 40 years. J Fam Plann Reprod Health Care 2005 Jan; 31(1):51-63; quiz 63. [147 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jan

GUI DELI NE DEVELOPER(S)

Faculty of Family Planning and Reproductive Health Care - Professional Association

SOURCE(S) OF FUNDING

Faculty of Family Planning and Reproductive Health Care

GUIDELINE COMMITTEE

Clinical Effectiveness Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Faculty</u> of <u>Family Planning and Reproductive Health Care Web site</u>.

Print copies: Available from the Faculty of Family Planning and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

A list of questions developed by the Faculty of Family Planning and Reproductive Health Care Education Committee is available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the <u>Faculty</u> of Family Planning and Reproductive Health Care Web site.

PATIENT RESOURCES

None available

NGC STATUS

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